

106TH CONGRESS
2D SESSION

H. R. 4483

To establish an Office on Women's Health within the Department of Health and Human Services, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MAY 17, 2000

Mrs. MORELLA (for herself and Mrs. MALONEY of New York) introduced the following bill; which was referred to the Committee on Commerce

A BILL

To establish an Office on Women's Health within the Department of Health and Human Services, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the "Women's Health Office
5 Act of 2000".

6 **SEC. 2. HEALTH AND HUMAN SERVICES OFFICE ON WOM-**
7 **EN'S HEALTH.**

8 Part A of title II of the Public Health Service Act
9 (42 U.S.C. 202 et seq.) is amended by adding at the end
10 the following:

1 **“SEC. 229. HEALTH AND HUMAN SERVICES OFFICE ON**
2 **WOMEN’S HEALTH.**

3 “(a) ESTABLISHMENT OF OFFICE.—There is estab-
4 lished within the Office of the Secretary an Office on
5 Women’s Health (referred to in this section as the ‘Of-
6 fice’). The Office on Women’s Health shall be headed by
7 a Deputy Assistant Secretary for Women’s Health.

8 “(b) DUTIES.—The Office shall, with respect to the
9 health concerns of women—

10 “(1) establish short-range and long-range goals
11 and objectives and coordinate all activities within the
12 Department of Health and Human Services that re-
13 late to disease prevention, health promotion, service
14 delivery, research, and public and health care profes-
15 sional education concerning women;

16 “(2) provide expert advice and consultation to
17 the Secretary concerning scientific, legal ethical, and
18 policy issues relating to women’s health;

19 “(3) monitor the Department of Health and
20 Human Services offices, agencies, and regional ac-
21 tivities regarding women’s health and stimulate ac-
22 tivities and facilitate coordination of such depart-
23 mental and agency offices on women’s health;

24 “(4) establish a Department of Health and
25 Human Services Coordinating Committee on Wom-
26 en’s Health to be chaired by the Deputy Assistant

1 Secretary for Women’s Health which shall be com-
2 posed of senior level representatives from each of the
3 agencies and offices of the Department of Health
4 and Human Services;

5 “(5) establish a National Women’s Health In-
6 formation Center to—

7 “(A) facilitate the exchange of information
8 regarding matters relating to health informa-
9 tion and health promotion, preventive health
10 services, research advances, and education in
11 the appropriate use of health care;

12 “(B) facilitate access to such information;

13 “(C) assist in the analysis of issues and
14 problems relating to the matters described in
15 this paragraph; and

16 “(D) provide technical assistance with re-
17 spect to the exchange of information (including
18 facilitating the development of materials for
19 such technical assistance);

20 “(6) coordinate efforts to promote women’s
21 health programs and policies in the private sector;
22 and

23 “(7) through publications and any other means
24 appropriate, provide for the exchange of information
25 between the Office and recipients of grants, con-

1 tracts, and agreements under subsection (c), and be-
2 tween the Office and health professionals and the
3 general public.

4 “(c) GRANTS AND CONTRACTS REGARDING DU-
5 TIES.—

6 “(1) AUTHORITY.—In carrying out subsection
7 (b), the Secretary, acting through the Office, may
8 make grants to, and enter into cooperative agree-
9 ments, contracts, and interagency agreements with
10 public and nonprofit private entities, agencies, and
11 organizations.

12 “(2) EVALUATION AND DISSEMINATION.—The
13 Office shall directly or through contracts with public
14 and private entities, agencies, and organization, pro-
15 vide for evaluations of projects carried out with fi-
16 nancial assistance provided under paragraph (1) and
17 for the dissemination of information developed as a
18 result of such projects.

19 “(d) REPORTS.—Not later than January 31, 2002,
20 and January 31 of each second year thereafter, the Sec-
21 retary shall prepare and submit to the appropriate com-
22 mittees of Congress a report describing the activities car-
23 ried out under this section during the period for which
24 the report is being prepared.

1 “(e) AUTHORIZATION OF APPROPRIATIONS.—For the
2 purpose of carrying out this section, there are authorized
3 to be appropriated such sums as may be necessary for
4 each of the fiscal years 2001 through 2005.

5 “(f) TRANSFER.—There are transferred to the Office,
6 all functions exercised by the Office on Women’s Health
7 of the Public Health Service prior to the date of enactment
8 of this section, including all personnel and compensation
9 authority, all delegation and assignment authority, and all
10 remaining appropriations. All orders, determinations,
11 rules, regulations, permits, agreements, grants, contracts,
12 certificates, licenses, registrations, privileges, and other
13 administrative actions—

14 “(1) which have been issued, made, granted, or
15 allowed to become effective by the President, any
16 Federal agency or official thereof, or by a court of
17 competent jurisdiction, in the performance of func-
18 tions which are transferred under this subsection;
19 and

20 “(2) which are in effect at the time this section
21 takes effect, or were final before the date of enact-
22 ment of this section and are to become effective on
23 or after such date;

24 shall continue in effect according to their terms until
25 modified, terminated, superseded, set aside, or revoked in

1 accordance with law by the President, the Deputy Assist-
 2 ant Secretary for Women’s Health or other authorized of-
 3 ficial, a court of competent jurisdiction, or by operation
 4 of law.”.

5 **SEC. 3. CENTERS FOR DISEASE CONTROL AND PREVEN-**
 6 **TION OFFICE OF WOMEN’S HEALTH.**

7 Part A of title III of the Public Health Service Act
 8 (42 U.S.C. 241 et seq.) is amended by adding at the end
 9 the following:

10 “CENTERS FOR DISEASE CONTROL AND PREVENTION
 11 OFFICE OF WOMEN’S HEALTH

12 “SEC. 310A. (a) ESTABLISHMENT.—There is estab-
 13 lished within the Office of the Director of the Centers for
 14 Disease Control and Prevention an office to be known as
 15 the Office of Women’s Health (referred to in this section
 16 as the ‘Office’). The Office shall be headed by a director
 17 who shall be appointed by the Director of such Centers.

18 “(b) PURPOSE.—The Director of the Office shall—

19 “(1) determine the current level of the Centers
 20 activity regarding women’s health conditions, across
 21 age, biological, and sociocultural contexts, in all as-
 22 pects of the Centers work, including prevention pro-
 23 grams, public and professional education, services,
 24 and treatment;

25 “(2) establish short-range and long-range goals
 26 and objectives for women’s health and coordinate all

1 other activities within the Centers that relate to pre-
2 vention, research, education and training, service de-
3 livery, and policy development;

4 “(3) identify projects in women’s health that
5 should be conducted or supported by the National
6 Centers;

7 “(4) consult with health professionals, non-
8 governmental organizations, consumer organizations,
9 women’s health professionals, and other individuals
10 and groups, as appropriate, on the policy of the Cen-
11 ters with regard to women; and

12 “(5) serve as a member of the Department of
13 Health and Human Services Coordinating Com-
14 mittee on Women’s Health (established under sec-
15 tion 229(b)(4)).

16 “(c) COORDINATING COMMITTEE.—

17 “(1) ESTABLISHMENT.—In carrying out sub-
18 section (b), the Director of the Office shall establish
19 a committee to be known as the Coordinating Com-
20 mittee on Research on Women’s Health (referred to
21 in this subsection as the ‘Coordinating Committee’).

22 “(2) COMPOSITION.—The Coordinating Com-
23 mittee shall be composed of the Directors of the Na-
24 tional Centers.

1 “(3) CHAIRPERSON.—The Director of the Of-
2 fice shall serve as the chairperson of the Coordi-
3 nating Committee.

4 “(4) DUTIES.—With respect to women’s health,
5 the Coordinating Committee shall assist the Director
6 of the Office in—

7 “(A) identifying the need for programs and
8 activities that focus on women’s health;

9 “(B) identifying needs regarding the co-
10 ordination of activities, including intramural
11 and extramural multidisciplinary activities; and

12 “(C) making recommendations to the Di-
13 rector of the Centers for Disease Control and
14 Prevention concerning findings made under
15 subparagraphs (A) and (B).

16 “(d) REPORTS.—Not later than January 31, 2002,
17 and January 31 of each second year thereafter, the Direc-
18 tor of the Office shall prepare and submit to the appro-
19 priate committees of Congress a report describing the ac-
20 tivities carried out under this section during the period
21 for which the report is being prepared.

22 “(e) DEFINITION.—As used in this section the term
23 ‘women’s health conditions’, with respect to women of all
24 age, ethnic, and racial groups, means all diseases, dis-
25 orders, and conditions—

1 “(1) unique to, more serious, or more prevalent
2 in women; and

3 “(2) for which the factors of medical risk or
4 type of medical intervention are different for women,
5 or for which it is unknown whether such factors or
6 types are different for women.

7 “(f) AUTHORIZATION OF APPROPRIATIONS.—For the
8 purpose of carrying out this section, there are authorized
9 to be appropriated such sums as may be necessary for
10 each of the fiscal years 2001 through 2005.”.

11 **SEC. 4. AGENCY FOR HEALTHCARE RESEARCH AND QUAL-**
12 **ITY OFFICE OF WOMEN'S HEALTH.**

13 Part C of title IX of the Public Health Service Act
14 (42 U.S.C. 299c et seq.) is amended—

15 (1) by redesignating section 928 as section 929;
16 and

17 (2) by inserting after section 927 the following:

18 **“SEC. 928. OFFICE OF WOMEN'S HEALTH.**

19 “(a) ESTABLISHMENT.—There is established within
20 the Office of the Director of the Agency for Healthcare
21 Research and Quality an office to be known as the Office
22 of Women's Health (referred to in this section as the ‘Of-
23 fice’). The Office shall be headed by a director who shall
24 be appointed by the Director of the Agency.

25 “(b) PURPOSE.—The Director of the Office shall—

1 “(1) determine the current Agency level of ac-
2 tivity regarding women’s health, across age, biologi-
3 cal, and sociocultural contexts, in all aspects of
4 Agency work, including development of evidence re-
5 ports and clinical practice protocols, and conducting
6 research into patient outcomes, delivery of health
7 care services, quality of care, and access to health
8 care;

9 “(2) establish short-range and long-range goals
10 and objectives for research important to women’s
11 health and coordinate all other activities within the
12 Agency that relate to health services and medical ef-
13 fectiveness research;

14 “(3) identify projects in women’s health that
15 should be conducted or supported by the Agency;

16 “(4) consult with health professionals, non-
17 governmental organizations, consumer organizations,
18 women’s health professionals, and other individuals
19 and groups, as appropriate, on Agency policy with
20 regard to women; and

21 “(5) serve as a member of the Department of
22 Health and Human Services Coordinating Com-
23 mittee on Women’s Health (established under sec-
24 tion 229(b)(4)).

25 “(c) COORDINATING COMMITTEE.—

1 “(1) ESTABLISHMENT.—In carrying out sub-
2 section (b), the Director of the Office shall establish
3 a committee to be known as the Coordinating Com-
4 mittee on Research on Women’s Health (referred to
5 in this subsection as the ‘Coordinating Committee’).

6 “(2) COMPOSITION.—The Coordinating Com-
7 mittee shall be composed of the Directors of the
8 Centers and Offices.

9 “(3) CHAIRPERSON.—The Director of the Of-
10 fice shall serve as the chairperson of the Coordi-
11 nating Committee.

12 “(4) DUTIES.—With respect to research on
13 women’s health, the Coordinating Committee shall
14 assist the Director of the Office in—

15 “(A) identifying the need for such re-
16 search, and making an estimate each fiscal year
17 of the funds needed to adequately support the
18 research;

19 “(B) identifying needs regarding the co-
20 ordination of research activities, including in-
21 tramural and extramural multidisciplinary ac-
22 tivities; and

23 “(C) making recommendations to the Di-
24 rector of the Agency concerning findings made
25 under subparagraphs (A) and (B).

1 “(d) REPORTS.—Not later than January 31, 2002,
 2 and January 31 of each second year thereafter, the Direc-
 3 tor of the Office shall prepare and submit to the appro-
 4 priate committees of Congress a report describing the ac-
 5 tivities carried out under this section during the period
 6 for which the report is being prepared.

7 “(e) AUTHORIZATION OF APPROPRIATIONS.—For the
 8 purpose of carrying out this section, there are authorized
 9 to be appropriated such sums as may be necessary for
 10 each of the fiscal years 2001 through 2005.”.

11 **SEC. 5. HEALTH RESOURCES AND SERVICES ADMINISTRA-**
 12 **TION OFFICE OF WOMEN’S HEALTH.**

13 Title VII of the Social Security Act (42 U.S.C. 901
 14 et seq.) is amended by adding at the end the following:

15 “OFFICE OF WOMEN’S HEALTH

16 “SEC. 713. (a) ESTABLISHMENT.—There is estab-
 17 lished within the Office of the Administrator of the Health
 18 Resources and Services Administration an office to be
 19 known as the Office of Women’s Health (referred to in
 20 this section as the ‘Office’). The Office shall be headed
 21 by a director who shall be appointed by the Administrator.

22 “(b) PURPOSE.—The Director of the Office shall—

23 “(1) determine the current Agency level of ac-
 24 tivity regarding women’s health across age, biologi-
 25 cal, and sociocultural contexts;

1 “(2) establish short-range and long-range goals
2 and objectives for women’s health and coordinate all
3 other activities within the Agency that relate to
4 health care provider training, health service delivery,
5 research, and demonstration projects;

6 “(3) identify projects in women’s health that
7 should be conducted or supported by the Bureaus;

8 “(4) consult with health professionals, non-gov-
9 ernmental organizations, consumer organizations,
10 women’s health professionals, and other individuals
11 and groups, as appropriate, on Agency policy with
12 regard to women; and

13 “(5) serve as a member of the Department of
14 Health and Human Services Coordinating Com-
15 mittee on Women’s Health (established under sec-
16 tion 229(b)(4) of the Public Health Service Act).

17 “(c) COORDINATING COMMITTEE.—

18 “(1) ESTABLISHMENT.—In carrying out sub-
19 section (b), the Director of the Office shall establish
20 a committee to be known as the Coordinating Com-
21 mittee on Research on Women’s Health (referred to
22 in this subsection as the ‘Coordinating Committee’).

23 “(2) COMPOSITION.—The Coordinating Com-
24 mittee shall be composed of the Directors of the
25 Bureaus.

1 “(3) CHAIRPERSON.—The Director of the Of-
2 fice shall serve as the Chairperson of the Coordi-
3 nating Committee.

4 “(4) DUTIES.—With respect to research on
5 women’s health, the Coordinating Committee shall
6 assist the Director of the Office in—

7 “(A) identifying the need for programs and
8 activities that focus on women’s health;

9 “(B) identifying needs regarding the co-
10 ordination of activities, including intramural
11 and extramural multidisciplinary activities; and

12 “(C) making recommendations to the Ad-
13 ministrator of the Health Resources and Serv-
14 ices Administration concerning findings made
15 under subparagraphs (A) and (B).

16 “(d) REPORTS.—Not later than January 31, 2002,
17 and January 31 of each second year thereafter, the Direc-
18 tor of the Office shall prepare and submit to the appro-
19 priate committees of Congress a report describing the ac-
20 tivities carried out under this section during the period
21 for which the report is being prepared.

22 “(e) AUTHORIZATION OF APPROPRIATIONS.—For the
23 purpose of carrying out this section, there are authorized
24 to be appropriated such sums as may be necessary for
25 each of the fiscal years 2001 through 2005.”.

1 **SEC. 6. FOOD AND DRUG ADMINISTRATION OFFICE OF**
2 **WOMEN'S HEALTH.**

3 Chapter IX of the Federal Food, Drug, and Cosmetic
4 Act (21 U.S.C. 391 et seq.) is amended by adding at the
5 end the following:

6 **“SEC. 908. OFFICE OF WOMEN'S HEALTH.**

7 “(a) ESTABLISHMENT.—There is established within
8 the Office of the Commissioner of the Food and Drug Ad-
9 ministration an office to be known as the Office of Wom-
10 en's Health (referred to in this section as the ‘Office’).
11 The Office shall be headed by a director who shall be ap-
12 pointed by the Commissioner.

13 “(b) PURPOSE.—The Director of the Office shall—

14 “(1) determine current Agency levels of activity
15 regarding women's participation in clinical trials and
16 the analysis of data by sex in the testing of drugs,
17 medical devices, biological products, and foods across
18 age, sociocultural, and where deemed appropriate,
19 biological contexts;

20 “(2) establish short-range and long-range goals
21 and objectives for all issues of women's health within
22 the jurisdiction of the Food and Drug Administra-
23 tion, including adequate inclusion of women and
24 analysis of data by sex in all Agency protocols and
25 policies;

1 “(3) provide guidance or criteria for drug, bio-
2 logics, and device manufacturers to use in deter-
3 mining the extent and sufficiency of female rep-
4 resentation in clinical trials and provide information
5 to women and health care providers on those areas
6 in which differences between men and women exist;

7 “(4) consult with pharmaceutical manufactur-
8 ers, health professionals with expertise in women’s
9 issues, consumer organizations, and women’s health
10 professionals on Agency policy with regard to
11 women;

12 “(5) make annual estimates of funds needed to
13 monitor clinical trials and analysis of data by sex in
14 accordance with needs that are identified; and

15 “(6) serve as a member of the Department of
16 Health and Human Services Coordinating Com-
17 mittee on Women’s Health (established under sec-
18 tion 229(b)(4) of the Public Health Service Act).

19 “(c) COORDINATING COMMITTEE.—

20 “(1) ESTABLISHMENT.—In carrying out sub-
21 section (b), the Director of the Office shall establish
22 a committee to be known as the Coordinating Com-
23 mittee on Women’s Health (referred to in this sub-
24 section as the ‘Coordinating Committee’).

1 “(2) COMPOSITION.—The Coordinating Com-
2 mittee shall be composed of the Directors of the
3 Food and Drug Administration Centers.

4 “(3) CHAIRPERSON.—The Director of the Of-
5 fice shall serve as the Chairperson of the Coordi-
6 nating Committee.

7 “(4) DUTIES.—With respect to studies on wom-
8 en’s health, the Coordinating Committee shall assist
9 the Director of the Office in—

10 “(A) identifying the need for further stud-
11 ies and issues in specific areas of women’s
12 health that fall within the mission of the Agen-
13 cy, and developing strategies to foster such
14 studies;

15 “(B) identifying needs regarding the co-
16 ordination of Agency activities, including inter-
17 nal and external activities;

18 “(C) maintaining the Agency’s focus in
19 areas of importance to women;

20 “(D) supporting the development of meth-
21 odologies to determine how to obtain data spe-
22 cific to women (including data relating to the
23 age of women and the membership of women in
24 ethnic or racial groups);

1 “(E) supporting the development and ex-
2 pansion of clinical trials of treatments and
3 therapies for which obtaining such data has
4 been determined to be an appropriate function;
5 and

6 “(F) encouraging the Food and Drug Ad-
7 ministration Centers to conduct and support
8 such studies, including such clinical trials.

9 “(d) REPORTS.—Not later than January 31, 2002,
10 and January 31 of each second year thereafter, the Direc-
11 tor of the Office shall prepare and submit to the appro-
12 priate committees of Congress a report describing the ac-
13 tivities carried out under this section during the period
14 for which the report is being prepared.

15 “(e) AUTHORIZATION OF APPROPRIATIONS.—For the
16 purpose of carrying out this section, there are authorized
17 to be appropriated such sums as may be necessary for
18 each of the fiscal years 2001 through 2005.”.

○